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RE: HU0001-11-1-TS13 (N11-C11) "Mentors Offering Maternal Support (MOMS): Building Resilient Families" PI: COL (ret) Weis

Dear Lt Col Hatzfeld:

Attached please find the final report for the above mentioned study.

If you have any questions regarding this request, please contact me at 253.682.3853 or by e-mail at etappero@genevausa.org.

Kind regards,

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Principal Investigator (Weis, Karen L.)

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Principal Investigator (Weis, Karen L.)

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PI Signature Karen L. Weis Date 25 October, 2017

Principal Investigator (Weis, Karen L.)

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Abstract

Purpose: Determine efficacy of Mentors Offering Maternal Support (M-O-M-STM) program for decreasing prenatal maternal anxiety and depression while building self-esteem and resilience and evaluate patterns of pro- and anti-inflammatory biomarkers in pregnancy and relationship to psychosocial measures.

Design: Randomized-controlled trial with repeated measures and interview data

Methods: Participants were randomized in first trimester to M-O-M-STM or prenatal care without M-O-M-STM. Measures of pregnancy anxiety, depression, self-esteem, and resilience were obtained in each trimester. Biomarkers, IL-6, TNF-alpha, IL-1B, IL-2, IL-10, CRP, and CRH and were collected at first trimester, 16 and 28-week lab draws. Telephone interviews were conducted with deployed husbands/fathers.

Sample: 246 pregnant military women completed the study. Sixty-six women completed biomarker element. Seven deployed husbands/fathers were interviewed.

Analysis: Linear mixed models were used to compare two-group differences in slopes of psychosocial measures and relationship of each to changes in biomarkers.

Findings: M-O-M-STM participants had significantly greater decreases in prenatal anxiety. Women with deployed spouses had higher depression scores and M-O-M-STM participation significantly decreased depression. Active duty women had significantly higher values for IL-6 and IL-10. Greater prenatal anxiety was significantly associated with elevated serum values for IL-10, TNF-alpha, and CRP. The themes from the interview data reflected the challenges of preparing for a life milestone while deployed, yet the element of "service before self" was predominant.

Implications for Military Nursing: Findings point to the success of a mentoring model for decreasing prenatal anxiety and depression. Prenatal screening for symptoms of depression is an established component of VA and DoD pregnancy guidelines. Assessment of prenatal anxiety and the treatment of both maternal anxiety and/or depression is not well defined. Prenatal anxiety is more prevalent than depression and predictive of postpartum depression, emphasizing the need for screening and treatment of both anxiety and symptoms of depression.

3

TSNRP Research Priorities that Study or Project Addresses
Primary Priority

| | |
|------------------------------------|---|
| Force Health Protection: | <input checked="" type="checkbox"/> Fit and ready force <input type="checkbox"/> Deploy with and care for the warrior <input type="checkbox"/> Care for all entrusted to our care |
| Nursing Competencies and Practice: | <input type="checkbox"/> Patient outcomes <input type="checkbox"/> Quality and safety <input type="checkbox"/> Translate research into practice/evidence-based practice <input type="checkbox"/> Clinical excellence <input type="checkbox"/> Knowledge management <input type="checkbox"/> Education and training |
| Leadership, Ethics, and Mentoring: | <input type="checkbox"/> Health policy <input type="checkbox"/> Recruitment and retention <input type="checkbox"/> Preparing tomorrow's leaders <input type="checkbox"/> Care of the caregiver |
| Other: | <input type="checkbox"/> |

Secondary Priority

| | |
|------------------------------------|---|
| Force Health Protection: | <input type="checkbox"/> Fit and ready force <input type="checkbox"/> Deploy with and care for the warrior <input checked="" type="checkbox"/> Care for all entrusted to our care |
| Nursing Competencies and Practice: | <input type="checkbox"/> Patient outcomes <input type="checkbox"/> Quality and safety <input type="checkbox"/> Nursing research into practice/evidence-based practice <input type="checkbox"/> Clinical excellence <input type="checkbox"/> Knowledge management <input type="checkbox"/> Education and training |
| Leadership, Ethics, and Mentoring: | <input type="checkbox"/> Health policy <input type="checkbox"/> Recruitment and retention <input type="checkbox"/> Preparing tomorrow's leaders <input type="checkbox"/> Care of the caregiver |
| Other: | <input type="checkbox"/> |

Progress Towards Achievement of Specific Aims of the Study or Project

The purpose of the research project was to:

Test the effectiveness and feasibility of a mentoring support program for decreasing prenatal maternal anxiety and depression while building self-esteem and resilience and evaluate the pattern of pro- and anti-inflammatory biomarkers in pregnancy and the relationship to the psychosocial measures.

The specific aims of the project were to:

1. Test the effectiveness of the Mentor's Offering Maternal Support (M-O-M-S™) program to build family fitness and resiliency of military wives.
2. Explore the impact of pregnant wives' contact with spouses through email and phone contact on presentism for duty and the military mission.
3. Examine the influence of psychosocial stress of pregnancy on the circulating levels of pro-inflammatory cytokines IL-6 and IL-1B, TNF- α and anti-inflammatory cytokines IL-2 and IL-10.
4. Investigate the impact of participation in the Mentors Offering Maternal Support (M-O-M-S™) intervention group on psychosocial stress of pregnancy, maternal cortisol, CRH, IL-6, IL-1B, TNF- α , IL-2 and IL-10.

The specific objectives of the program were:

Determine the impact of the M-O-M-S™ program to:

1. Build self-esteem, coping skills, and family cohesion/unity and adaptability.
2. Decrease prenatal maternal anxiety and stress.
3. Explore the husbands' perception of the benefits of the M-O-M-S™ program for decreasing their wives' maternal anxiety.
4. Explore the concept of presentism for work for spouses experiencing greater than a 30 day absence from the home during the course of pregnancy.

The hypotheses for aims 3 and 4 include:

- H1.1. Psychosocial stress of pregnancy promotes production of pro-inflammatory cytokines, IL-6, IL-1B, and TNF- α .
- H1.2. Psychosocial stress of pregnancy inhibits the production of anti-inflammatory cytokines, IL-2 and IL-10.
- H2.1. Participation in the M-O-M-S™ program ameliorates the psychosocial stress of pregnancy.
- H2.2. M-O-M-S™ participant summary scores on the COPE psychosocial stress scale will be associated with increased cortisol, CRH, and pro-inflammatory cytokines.

The primary aim of the study was to test the effectiveness of the Mentors Offering Maternal Support (M-O-M-S™) program at decreasing maternal anxiety, stress, and depression while building self-esteem, coping skills, and family cohesion and adaptability. Additionally, the association of psychosocial measures of stress and anxiety during pregnancy to pro- and anti-inflammatory cytokines was assessed. Following IRB approval, pregnant military beneficiaries within the San Antonio Military community were contacted regarding interest in the study. Women were eligible to participate in the study if they were: 1) in their first trimester of

pregnancy, 2) at least 18 years old, and 3) a wife or an active duty member of one of the American Armed Services. From June 20, 2012 to June 16, 2015, 1128 women did not meet inclusion criteria, 243 chose not to participate, and 367 women were consented and randomized to the M-O-M-S™ study (Figure 1). Two hundred and forty-six women completed data collection across the three trimesters of pregnancy and were included in the data analysis regarding the efficacy of the M-O-M-S™ for decreasing prenatal anxiety, stress, and depression while building self-esteem, coping skills, and resilience.

The women consented to the M-O-M-S™ study were randomized to either the treatment or control group. The computer-generated randomization pattern was developed prior to participant enrollment, and was based on random selection without stratification. Therefore, the groups included an unequal number of participants with differing group means for the baseline measures. All participants were recruited in the first trimester of pregnancy and completed the initial questionnaire booklet, containing the psychosocial measures and demographic data forms. Questionnaires were also completed in the second and third trimesters of pregnancy. Pregnancy and birth outcomes data were obtained from the maternal and infant inpatient delivery records. Table 1 provides an overview of the specific measures aligned with the concepts of pregnancy anxiety and stress, self-esteem, depression, resilience, coping, and family adaptability and cohesion.

Women randomized to the treatment group, were registered for a M-O-M-S™ group. Each group began in the first trimester and included eight sessions offered for one hour every-other week. The program was designed predominantly for the first and second trimesters of pregnancy when the woman's prenatal pregnancy-specific anxiety is known to be the highest (Lederman & Weis, 2009). Each class was facilitated by one or two mentors. The mentors were women who were/are married to military members and who are mothers. All mentors received formal training on the theoretical underpinnings of the M-O-M-S™ program and the intended focus of each class. The training also included aspects of conducting a research intervention and the need to provide the M-O-M-S™ program consistently across all groups. Both the treatment and control groups received standard prenatal care.

During the course of recruiting for the M-O-M-S™ study, women were asked if the spouses were going to be deployed during the course of their pregnancies. If the potential existed, the research team maintained ongoing dialogue with these mothers regarding the deployment window. Spouses agreeing to participate in this component of the study were contacted by telephone while deployed (primarily) and interviewed.

An additional component of the M-O-M-S™ study was the assessment of biomarkers across pregnancy. Women consented for Phase I (the original M-O-M-S™) were recruited and consented for participation in the biomarker component of the study. Women consented to participate in this phase ($n = 66$) had an additional serum tube drawn at their 1st trimester, 16-week and 28-week lab draws. The samples were collected by the laboratory phlebotomist and then centrifuged. Once centrifuged, the specimens were aliquoted and frozen at -80 for batch analysis by trimester. IL-6, TNF- α , IL-1B, IL-2, IL-10, CRP, and CRH were analyzed in duplicate by ELISA. Maternal cortisol levels were determined by measuring unbound cortisol in serum. At the time of laboratory data collection, the participants were met by a Research

Assistant and given a questionnaire booklet with the measures of psychosocial stress in pregnancy, self-esteem, coping, and depression. The participants' blood pressure and temperature were taken at the same time to determine if they were febrile or showing any flu-like symptoms that could alter the laboratory data. Fifty-eight women completed all aspects of this element of the study.

Findings related to each specific aim, research or study questions, and/or hypothesis:

The primary aim of the study was to assess the efficacy of the M-O-M-S™ program to build family fitness and resilience while decreasing pregnancy anxiety, stress, and depression.

To examine the efficacy of the intervention across pregnancy for prenatal anxiety, self-esteem, depression, resilience, and family fitness, linear mixed models with autoregressive correlation structure of order were adopted. Individual measurement times (week's gestation at data collection) and group assignment and their interaction were included within the models with and without adjusting for the participant's age (continuous variable), employment status (yes or no), prior deliveries (0 or >0), marital status (yes or no), education (high school, some college, college graduate), deployment of partner during pregnancy (yes or no), military service branch of participant or spouse (Air Force, Army, Navy, and Marine), ethnicity (Caucasian or other), and military rank of participant or spouse (E1-E4; E5-E9; W1-W4; officer, and not in military) to determine differences in the slope for each dependent variable. In the case of dual military couples, the rank and service of the active duty woman was used. The final model was obtained by backward elimination procedure.

Of the 246 participants who completed all aspects of the study, the majority of the sample were Caucasian (60%), had a college degree (42%), were employed (63%), and married (91%). Forty percent of the sample were active duty and 94 (38%) of the participants were pregnant with their first child. Twenty-one (9%) women experienced deployment of their spouse during pregnancy. The women ranged in age from 19-42 ($M = 28.72$, $SD = 5.00$). The mean gestational age at entry into the study was 9 weeks ($SD = 2.47$). The intervention and control groups were similar for all demographic characteristics except marital and active duty status and military rank (Weis, Lederman, Walker & Chan, 2017).

Note: The demographic table is not included as we are unable to make substantial changes to the information or data and it is published and available in JOGNN (2017). 46(3) pp. 660-668. The regression models are in this manuscript.

The Prenatal Self-Evaluation Questionnaire (PSEQ) scales measured pregnancy-specific anxiety or dimensions of anxiety. For both the unadjusted and adjusted models with each of the seven scales of the PSEQ, two of the seven scales (dimensions) of prenatal anxiety reflected significant (or borderline significant) variation over time, with the participants of the M-O-M-S™ program indicating greater decreases in anxiety for *Identification with a Motherhood Role* (slope decrease = 0.03, $p = .055$ (unadjusted); slope decrease = 0.03, $p = .049$ (final)) and *Preparation for Labor* (slope decrease = 0.06, $p = .018$; slope decrease = 0.06, $p = 0.017$). Parity was a significant covariate within the model as a predictor of anxiety. Nulliparous women had significantly lower anxiety for *Acceptance of Pregnancy* than the multigravidas, with anxiety 1.32 units lower ($se = 0.55$; $p = .018$) than that of the multigravidas. Nulliparous women had significant increases over

those of the multigravida for anxiety related to *Preparation for Labor* (5.01 unit increase, $se = 0.51$; $p < .0001$), and *Pain, Helplessness, and Loss of Control in Labor* (1.19 unit increase, $se = 0.41$; $p = .004$). Unmarried women (all active duty participants) had significantly higher anxiety related to *Acceptance of Pregnancy*. *Concerns for Well-Being of Self and Baby in Labor* ($p < .0001$; $p = .014$). Deployment of one's spouse for at least 30 days during pregnancy significantly increased anxiety related to *Identification with a Motherhood Role*. This was the only covariate to remain in the model for *Identification with a Motherhood Role* and the anxiety increased by 1.04 units ($se = 0.50$; $p = .041$) over those not experiencing deployments (Weis et al., 2017).

In the primary mixed models that assessed individual differences in slopes for each variable of anxiety over time, there were no significant changes in participant scores for the measure of depression. However, when differences between the first and third trimester were assessed between the treatment and control groups for symptoms of depression with deployment, the interaction term of deployment with treatment group assignment showed that women with deployed husbands, and attending the M-O-M-STM program, had significant decreases in depression scores ($\beta = 15.40$, $p = .000$) (Figure 2). Apart from group participation, women not experiencing deployment of spouses had significantly lower depression scores ($\beta = -3.82$, $p = .022$).

The scores for self-esteem did not increase significantly for participants within the M-O-M-STM program. The intercept for the sample was 35.56, indicating very high scores for self-esteem at baseline (range of possible scores 10-40). In the final adjusted model, ethnicity and military rank of one's spouse were significant predictors of self-esteem. Women of color had a 1.96 unit increase in their scores for self-esteem over the Caucasian women in the study ($se = 0.47$, $p < .0001$) (Weis et al., 2017).

In both the unadjusted and adjusted models with *Resilience* as the outcome variable, there was a statistically significant increase in the scores for both the treatment and control groups across pregnancy ($\beta = 0.04$, $p = .02$). Marital status, education, and military service branch were significant predictors of resilience. Not being married increased one's resilience ($se = .75$, $p = .006$), while those with a high school education had lower resilience compared to those having some college education or college graduates ($\beta = 2.46$, $p = .003$; $\beta = 2.14$, $p = .008$). The Marine and Coast Guard participants had the highest scores for resilience.

Scores for family adaptability and cohesion did not increase significantly for participants in the M-O-M-STM. Similarly, coping scores did not differ significantly between the treatment and control groups.

The second aim of the project was to explore contact with deployed spouses and the impact on their presentism for duty and the military mission. This aim aligned with the third objective to explore the husbands' perceptions of the benefits of the M-O-M-STM program for decreasing their wives' maternal anxiety. The original intent of the study was to interview the husbands upon their return and correlate their responses with the wives' anxiety and family adaptability measures. During meetings with the team prior to study roll-out, there were concerns expressed that in waiting until the husbands return from deployment to capture data, perceptions might change from those held during the deployment.

On 6 November 2012, an amendment was submitted to conduct phone interviews with the husbands during their deployments versus waiting until their return. This amendment was approved and the study design was changed to accommodate phone interviews during the course of the husbands' deployments.

Every attempt was made to align the interview with the wives' second trimester while also waiting at least 3 weeks into the husband's deployment. From 1 September 2013 to 31 July 2014, 7 participants geographically separated from their wives were interviewed. Telephone interviews using a semi-structured interview format were audio recorded using the TelcoDepot telephone recorder backed up with an Olympus VN-8100PC digital recorder. The central organizing theme of data collection was the experience of deployment during the military member's wife's pregnancy. The audio recordings were transcribed fully verbatim by a professional transcription company and reviewed for accuracy. Exploration of the transcripts involved 6 phases of analysis facilitated through use of Ethnograph v6 software: 1) initial coding and identifying major themes of participant narratives, 2) development of précis of overall gestalt of each participant's narrative, 3) three successive meetings with the PI and an AI to establish consensus or challenge assumptions of initial coding, 4) in depth coding including identification of attributes and subcodes characterized within the narrative structure, 5) development of stanzas and lines that characterize idea units embedded in the discourse, and 6) examination of patterns and links within and across individual participant narratives.

Analyses depicts the challenges these 7 service members experienced as they attempted to reconcile the interplay of their military and social identities.

Themes of Interviews with Dads

Getting the Walk Down: refers to learning from other fathers how they manage 'the walk' - the dual responsibilities of duty requirements and pregnant wife at home. *I can be very bull-headed sometimes and not really understanding, so, just kind of talking with other married guys who have kind of been in the same situation I am in telling me like, Hey, man, look, I know what you want to do...you've got to put mama ahead.*

Band of Brothers: Refers to the support service members derive from the camaraderie with other service members going through the same thing - the ones who have experienced pregnancy during deployment offer support, strategies and recommendations for how to communicate with wives, how to stay focused on job, etc.

There's really no one else here going through the same thing right now. Pretty much everyone in the command, but only two are higher than me, I've told them both. They say whenever the birth happens I can take that day off, they've been good about it.

A Picture and a Voice: Refers to how service members feel with children at home. They speak to the children by telephone, Skype, etc. but it's not the same as being there. Members voiced the burden they placed on their children and the guilt that felt about not being able to be at home. *I always think of that country song...watching the kids grow up in pictures. It's frustrating, painful. I see the pictures and I hear their voices but it doesn't help.*

Absent but Present: Although service members were geographically separated from their wives and family they made a concerted effort to communicate by phone, Skype, FaceTime or through letters and cards to try to participate in family life during deployment to the degree they could. *It's frustrating not being with her during the pregnancy. I try to call or at least get on facebook with her once a day, but it's not the same. And as often as I can I try to get on Skype, so there's a little face time but it's not as often as we want. That's about as much support as I can give her not being there. There are a lot of things she has to handle in the household. It's a lot for her to handle being pregnant. It's frustrating. I don't know what else to do at this point. You know. I can't fly back to the States every day.*

She's Got the Conn: Although service members were concerned and sometimes worried, they felt confident that their wives were able to handle the situation while they were away. In other words, she's in charge. In the movie *Star Trek*, when the Captain leaves the Bridge, they say, 'You've got the Conn', meaning the other person is in charge. *I don't worry our kids with her. That's the last thing on my mind is if she can handle it or not. She does a helluva job. At first it was like, I'm the man, I make the decisions, but, you know, that doesn't work too well. That, that'll, that might get you shot (laughing). No, we talk about things a lot and I support her in her decisions.*

Married to the Military: This theme refers to the inherent role women married to service members must take on in order that their husbands can serve in the military, i.e., they raise the children when the husbands aren't there, manage the household, finances and other aspects of family life. *We've talked about it. I said (to his wife). Hey, look, I'm fine with not putting this thing (application for Warrant Officer) in. You know, we discussed it. I said, "But, if I do put it in, the chances of me, I will be gone for about the first two, two and a half years. I'm going to be here a lot. You know, out of those 24 months, you know, I'll probably be there, be around you and the kids for maybe five or six of them. If she wasn't with me putting that packet in and, and with me being gone like this, I wouldn't have put it in.*

The Job Becomes Your Life: To the person, every service member cited, 'service before self' as a way of life in the military. The data that informed this theme underscored the deployed service member's (dad's) ability to focus on duty requirements (presentism) while geographically separated from his pregnant wife. *I worry when I am off from work - there is no time to think about it or worry at work - it's just too busy. I run every night to blow off steam - it's a big stress reliever but I try not to tell her too much so she doesn't worry. It stinks that I won't be there for the delivery but she'll be in the hospital where she'll get good care. I mean, I'd like to be there but it's for a greater cause, so you know. I can't really complain too much.*

The stanza analyses below provides an additional perspective.

We're There As Well/You Don't See the Father

She's going through it all
We're there as well
And deployed
You don't know
You don't see the father
So you don't know
No one knows
What he's going through
There's a lot going through his head
A lot of emotions
You know

The themes and quotes above are extracts from longer narratives deployed service members told about their experience of being absent during their wife's pregnancy. They illustrate the challenges deployment may impose on members, their spouses and their families. In particular, these narratives represent various aspects of the internal tension deployed members may confront when facing concomitant commitments - allegiance to the core value of 'service before self' and their responsibility within the context of a life milestone.

The third and fourth aims of the study were to examine the influence of psychosocial stress of pregnancy on the circulating levels of pro-inflammatory cytokines IL-6 and IL-1 β , TNF- α and anti-inflammatory cytokines IL-2 and IL-10 and the impact of the M-O-M-STM intervention group on psychosocial stress of pregnancy, maternal cortisol, CRH, IL-6, IL-1 β , TNF- α and IL-10.

Differences in the biomarkers for the intervention and control groups were assessed. There were no significant differences between the treatment and control groups for any of the biomarkers. The control group did have significantly lower levels of IL-10 at baseline ($\beta = -.945$; $se = 0.30$; $p = .003$) and they had lower anxiety levels than the treatment group. Over the course of pregnancy, for both groups, IL-6 had a slight but significant increase ($\beta = .002$; $se = 0.00$; $p = .005$), as did CRP ($\beta = .053$; $se = 0.01$; $p = .000$), CRH ($\beta = .085$; $se = 0.01$; $p = .000$), and serum cortisol ($\beta = .034$; $se = 0.00$; $p = .000$). There was a borderline significant decrease in TNA-alpha over the course of pregnancy ($\beta = -.010$; $se = 0.00$; $p = .06$).

There were significant relationships between prenatal psychosocial measures of anxiety and depression and levels of serum cytokines across pregnancy. Regression analysis showed that elevated levels of prenatal pregnancy-specific anxiety were significantly related to elevated values for anti-inflammatory marker IL-10. The overall score for prenatal anxiety measured with the *Prenatal Self-Evaluation Questionnaire* (PSEQ-SF) was significantly related to elevated values for IL-10 ($\beta = .01$; $se = 0.01$; $p = .03$), as were the individual scales for *Identification with a Motherhood Role* ($\beta = .08$; $se = 0.03$; $p = .01$) and *Relationship with Husband/Partner* ($\beta = .06$; $se = 0.02$; $p = .00$). Anxiety related to *Identification with a Motherhood Role* was significantly

related to elevated values for pro-inflammatory marker TNF-alpha ($\beta = .05$; $se = 0.02$; $p = .02$). Elevated levels of anxiety related to *Preparation for Labor* were found to be significantly related to decreased values for C-reactive protein ($\beta = -.05$; $se = 0.02$; $p = .03$). Elevated overall scores for prenatal anxiety were significantly related to decreased values of Corticotropin-Releasing Hormone (CRH) ($\beta = -.01$; $se = 0.00$; $p = .05$) as were elevated values for anxiety related to *Acceptance of Pregnancy* ($\beta = -.04$; $se = 0.02$; $p = .04$). Lastly, decreased scores for self-esteem were significantly related to elevated serum levels of pro-inflammatory marker IL-6 ($\beta = -.01$; $se = 0.00$; $p = .05$).

In the course of analyzing the biomarker data, comparisons were made between the biomarkers of active duty and civilian participants. For the interaction of active duty status by time, active duty women had statistically significant higher values over time for the pro-inflammatory cytokine IL-6 ($\beta = .008$; $se = 0.00$; $p = .02$) than the civilian wives in the study, and statistically significant higher values for the anti-inflammatory cytokine IL-10 ($\beta = .028$; $se = 0.01$; $p = .03$). When assessing the interaction of active duty status and anxiety/depression measures on serum biomarkers, we found that the interaction of active duty status and scores for symptoms of depression were significantly related to elevated values for IL-1B (Fig. 3).

Relationship of current findings to previous findings:

The evaluation of the M-O-M-STM program culminates a 15-year process by which data were collected from 321 women over the course of pregnancy to determine program foci (Weis, Lederman, Lilly, & Schaffer, 2008), and once developed, the program was piloted with 65 military women (Weis & Ryan, 2012). Findings from the initial work yielded data regarding the type of anxiety and the prenatal timepoints of maternal anxiety that were associated with poor outcomes (primarily first and second trimesters). It was also determined that pregnant military wives and active duty women desired esteem-building support from a military community network rather than a non-military community (Lederman & Weis, 2009). The need for support specifically from a military community formed the foundation of the mentor program. The components of the program aligned with the theoretical foundations of psychosocial adaptation to pregnancy and the 7 dimensions of pregnancy-specific anxiety previously found to be predictive of preterm birth and low birthweight (Lederman & Weis, 2009).

The pilot work for the M-O-M-STM program was completed with women experiencing deployment of their spouses during pregnancy. Not unexpectedly, the means of the pilot sample for the 7 dimensions of pregnancy-specific anxiety were higher than in the current sample in which only 9% of the sample experienced deployment (Weis et al., 2017). However, the dimension with the highest scores was *Identification with a Motherhood Role*. Similarly, this study found that deployment of one's spouse had a statistically significant increase in the anxiety related to *Identification with a Motherhood Role*. It was the only dimension of anxiety that was impacted by deployment. The findings reflect the significance of the spouse's presence to the internalization of the woman's maternal identity (Weis et al., 2017). During the pilot work, we found that the women having the greatest contact with their spouses had the highest scores for self-esteem (Weis & Ryan, 2012). Self-esteem is intricately linked to development of one's identity as a mother (Lederman & Weis, 2009).

In our initial work with a military sample, we found that pregnancy-specific anxiety related to *Acceptance of Pregnancy*, *Identification with a Motherhood Role*, *Preparation for Labor*, and

Concerns for Well-Being of Self and Baby were predictive of having early for gestational age infants (Lederman & Weis, 2009). Anxiety related to *Preparation for Labor and Fear of Pain, Helplessness, and Loss of Control in Labor* were predictive of having lower infant birthweights (Lederman & Weis, 2009). In this study, we showed that the M-O-M-STM was effective at decreasing anxiety related to *Preparation for Labor and Identification with a Motherhood Role*. We were unable to assess the direct effects of the M-O-M-STM intervention on birth outcomes secondary to sample size but we did find that across the entire sample, anxiety related to *Acceptance of Pregnancy*, *Preparation for Labor*, and *Helplessness, and Loss of Control in Labor* were significant predictors of early for gestational age (EGA) infants ($p = .008$; $p = .002$; $p = .00$ respectively). Anxiety related to *Concerns for Well-Being of Self and Baby* was a significant predictor of low infant birthweight ($p = .03$). Additionally, for the models specifically looking at infant birthweight as the outcome measure, active duty status was significant in each model. The findings reflect that the women on active duty had a statistically greater likelihood of having an infant of lower birthweight than the civilian women in the study.

The data from the interviews with the fathers represent the only data of its type. The interviews are striking in that they provide important insight regarding the deployed father's feelings of his wife's pregnancy and the impact of his absence on himself and the family.

Effect of problems or obstacles on the results:

The greatest obstacle encountered over the course of the study was the change in the primary women's health clinics and location of military deliveries for the San Antonio military community. The closure of Wilford Hall Medical Center and the creation of the San Antonio Military Medical Center (SAMMC) led to the women's health clinic at SAMMC providing the bulk of prenatal care for the military community. The Wilford Hall Ambulatory Care Facility (WHASC) maintained a women's health clinic but the numbers dropped substantially during the course of the study. We had IRB approval and letters of support from both facilities; however, the support for conducting the M-O-M-STM program and recruiting patients was greater at the WHASC. Therefore, our numbers were substantially lower than originally anticipated. The number of available, eligible patients was also affected by the change in TriCare reimbursement for prenatal care and deliveries obtained outside the military network. We had a higher than anticipated number of women who entered prenatal care after the first trimester. This was not due to late entry into prenatal care but due to military moves. We had not seen these types of numbers in previous recruitment and believe the shift may have been related to the myriad of unit realignments that occurred across all the services during the period of this study.

When the biomarker portion of the study began, we had opted to recruit exclusively from the WHASC as that was where we had the support within the laboratory for drawing the specimens, spinning down the specimens, and storage. The need to hire special transport services for the biologic specimens from SAMMC to the WHASC clinical research department precluded our ability to collect specimens at both locations. This decreased the final sample of biomarkers substantially. We did obtain almost 100% participation from the women having their prenatal care at the WHASC.

The original intention of the study was to compare the effectiveness of the M-O-M-STM combined with the Centering Pregnancy program. Before the study could start, the Centering

Pregnancy numbers had dwindled too low to allow for any statistical comparisons or group randomization.

The original study objectives included an objective to mentor an Air Force doctoral nursing student. The student opted to take a different focus during her doctoral studies and did not participate in the study.

Limitations:

The goal of any intervention research is to demonstrate the efficacy of a treatment or intervention. In an effort to increase internal validity and be able to determine causal relationships, an experimental design with random assignment was selected. However, simple random assignment of participants to treatment or control groups does not guarantee the groups will be comparable (Zeller, Good, Anderson, & Zeller, 1997). Instead, random selection based on determined covariates is required to eliminate these differences. Stratification of the sample based on selected covariates was not included within the study design. The intervention and control groups were similar for all demographic characteristics except marital and active duty status and military rank. The control group contained a significantly higher percentage of married women, were less likely to be on active duty, and their husbands were of higher rank. These variables were added to the models in order to address the group differences.

Data were collected in each trimester of pregnancy. However, the inclusion of only one assessment in each trimester limited the ability to determine change secondary to the intervention rather than change occurring due to maturation or normal adaptation of pregnancy (Weis et al., 2017). The intervention was started in the first trimester in order to focus on anxiety related to acceptance and identification with a motherhood role. The baseline data were taken in the first trimester prior to any intervention. The next data collection point was in the second trimester. Additional data collection points early in pregnancy would help improve the ability to assess changes related directly to the intervention.

The sample was quite large for a complex randomized study. But the sample was predominantly Air Force and Caucasian. The sample size was not large enough to allow for the analyses of the intervention effects on pregnancy complications and birth outcomes. Instead, we were able to assess outcomes for the entire sample. The primary focus of the military community where recruitment took place was training rather than operational missions. There were fewer deployments and family separations. The mission focus may affect generalizability of the data to a larger military population. It is likely that a military sample with a higher readiness posture would lead to greater anxiety in the family and particularly for pregnant military wives. A larger, multi-site study is needed to evaluate mission and service differences and add greater diversity. A larger sample of at least 900 women is needed to compare pregnancy and birth outcomes for the intervention.

Recruiting, consenting and contacting the "dad" participants was difficult. There were only 21 women in the study who experienced deployment of their husbands during the course of pregnancy. This limited our ability to recruit the dads. We tried to recruit and consent the fathers in the study prior to their deployment. We attempted to sync the interview with a mid-pregnancy time point, while considering the time that the husband/dad had been absent from the

home. Admittedly, we did not want to interview the husband/dad as they were preparing to come home or just as they were arriving in theater as we wanted the feelings related to the absence from the wife & family to be the underlying element of the interview. This was difficult with also juggling the time difference and being able to establish a date and time for the interview. While we were able to capture relevant data with this design approach, it was difficult.

Conclusion:

Much of the focus related to prenatal anxiety and depression has been placed on screening (Yawn, LaRusso, Bertram, & Bobo, 2015). But screening alone does not improve outcomes and studies have shown that referrals are not an effective approach for providing prenatal care to women who screen positive for prenatal depression (Kozhimannil, Adams, Soumerai, Busch, & Huskamp, 2011; Yawn et al., 2012) and most likely anxiety. The M-O-M-STM program offers a low to no-cost intervention that is modeled upon a community-type partnership in which military wives/mothers mentor and support pregnant women. The M-O-M-STM program has shown efficacy for decreasing prenatal maternal anxiety, specifically that related to *Preparation for Labor and Identification with a Motherhood Role*. Deployment was found to be the one variable that significantly affected anxiety related to *Identification with a Motherhood Role*. As early as the first trimester, an expectant mother searches for information (Deutsch et al., 1988). She is beginning the process of disengaging from her identity as a woman without a child to a woman with a child (Lederman & Weis, 2009; Rubin, 1984). Information is sought from women friends who can share and listen. In the first trimester, the woman may limit her pregnancy announcement to the father of her baby, her mother and closest friends. It is this small network of friends and family that are most likely to provide intimate care, protection, and supportive nurturance (Rubin, 1984). Our findings reflect the importance of the husband's supportive presence to maternal identity formation. For military women separated from their close network of friends and family and perhaps their husbands, it is doubly important to create a close network that can provide the protective, esteem-building support needed for building maternal identification. Women within the M-O-M-STM group had significantly lower anxiety related to *Identification with a Motherhood Role*. Identifying with a motherhood role is a critical task of pregnancy (Lederman & Weis, 2009) and is predictive of postpartum maternal-infant attachment (Slade, Grienemberger, Bernbach, Levy, & Locker, 2005).

The interviews provided insight that active duty fathers with pregnant wives at home continued to put the mission first. They all described feeling anxiety over the safety of their wives and concerns over pregnancy complications. They felt that the support they derived from other active duty, deployed fathers helped them through the difficult separation. Given the significance of the deployed husband on the woman's anxiety regarding *Identification with a Motherhood Role*, being able to maintain any type of contact is important to the woman's overall well-being.

There is an emerging body of evidence linking prenatal maternal anxiety to changes in the immune function and poor pregnancy, birth and infant outcomes (Coussons-Read, Okun, Schmitt, & Giese, 2005; Entringer, Buss, & Wadhwa, 2012). Cytokines produced by cells of the immune system during stress and infections are involved in both the maintenance of pregnancy and onset of labor (Elenkov & Chouros, 1999). Therefore, evaluating alterations in cytokines

during pregnancy is quite complex. Coussons-Read, Okun, and Nettles (2007) reported increased serum levels of IL-6 and reduced levels of IL-10 in women reporting high stress across pregnancy, and elevated serum CRP was found in women having elevated stress in mid-pregnancy with low social support. We did not find any associations between the biomarkers and our measure of social support. It may be that social support is acting as a mediator rather than having a main effect within the model. We have not tested this theory. Coussons-Read et al (2007) found increasing levels of IL-6, IL-10, and TNF-alpha across pregnancy. In our sample, there were statistically significant increases in the serum levels for IL-6, CRP, CRH and cortisol across pregnancy. There was a borderline significant increase in TNF-alpha ($p < .07$). The serum levels for IL-10 did not significantly increase across pregnancy.

Elevated serum levels of IL-6 and TNF-alpha have been associated with premature labor and delivery (Zhang, Wang, Zhao, & Kang, 2000). We found a significant relationship between anxiety related to *Identification with a Motherhood Role* and TNF-alpha. This dimension of anxiety was previously found to predict early gestational age (Lederman & Weis, 2009). Elevated serum levels of CRP have been reported in pregnant women having elevated levels of stress and were also found to be predictive of the development of preeclampsia and premature rupture of membranes (Coussons-Read, Okun, & Nettles, 2007; Kumru, Godekmerdan, Kutlu, & Ozcan, 2006; Teran, Escudero, & Calle, 2005). We found that elevated levels of prenatal anxiety related to *Preparation for Labor* were associated with increased CRP. Anxiety related to *Preparation for Labor* was found to predict early gestational age in this sample and a previous sample (Lederman & Weis, 2009). As pregnancy advances, levels of CRH increase because of a maternal-placental circuit (Davis et al., 2005). However, elevated concentrations of CRH are associated with preterm birth (Davis et al) and medically complicated pregnancies (Harville, Savitz, Dole, Herring, & Thorp, 2009). We found a statistically significant inverse relationship between CRH levels and prenatal anxiety, specifically *Acceptance of Pregnancy* and the total scale score. Given that CRH concentrations rise over 1000-fold in pregnancy (Gangestad, Hooper, & Eaton, 2012), and the scores for acceptance gradually decline over the course of pregnancy (Lederman & Weis, 2009), this association may be a naturally occurring phenomenon rather than an indication of any adverse relationship secondary to stress. It could be a similar situation with the total scale score.

In our sample, the active duty women had significantly higher values for IL-6 and for IL-10 than the civilian women. There were no significant differences for TNF-alpha, CRP, CRH or cortisol. We recognized that the active duty variable may have been a proxy variable for something else like BMI, sleep, or activity levels. This data was captured separately and assessed within the biomarker models. None of the covariates were significant within the models, yet active duty status remained significant. Active duty women were also found to have higher scores for symptoms of depression which related to significantly higher values for IL-6B. Coussons-Read et al. found that women in the highest stress group produced significantly more IL-1B and IL-6 than women in the low stress group. There is a strong correlation with prenatal anxiety and depression (Gavin, Meltzer-Brody, Glover, & Gaynes, 2015).

Most commonly, the statistical models reflecting significance were those that included scales measuring elements of maternal identity formation. Increased anxiety related to *Identification with a Motherhood Role* was associated with elevated values for IL-10 and TNF-alpha. While

not reported in the results, we found borderline significant results for an inverse relationship between *Identification with the Motherhood Role* and values for CRP and IL-2. The woman's ability to identify with being a mother affects her ability to prepare for the delivery and to attach with the fetus and later the infant. *Acceptance of Pregnancy* is closely aligned with one's maternal identity formation and both prenatal anxiety for *Identification with the Motherhood Role* and *Acceptance of Pregnancy* were found to predict preterm birth. There is nothing pre-programmed regarding maternal behaviors, but during pregnancy there is a psychological process running parallel with the biological development of the fetus in which the mother identifies with the unity of herself and the fetus (Rubin, 1984). For the most part, anxiety regarding maternal identification can only be alleviated through intervention. The M-O-M-STM program decreased the anxiety the women had for *Identification with the Motherhood Role*.

Significance of Study or Project Results to Military Nursing

The complex relationship between perinatal health care and mental health requires a multidisciplinary undertaking (O'Hara, Dennis, McCabe & Galbally, 2015). Perinatal and obstetrical nurses are particularly well-suited to conduct assessment and interventions for prenatal maternal anxiety and depression. Successful screening programs require available support for the women (Gemmell, Milgrom, & Highet, 2015). Few if any health care professionals spend more time with the pregnant woman and the family than the nurse. Military nurses understand the stress of being a military family and many are mothers. The findings from this study point to the success of a mentoring model for decreasing prenatal anxiety. Obstetrical nurses are the best prepared to mentor and support the military mothers as they understand the underlying theories guiding the intervention. Evidence points towards the effectiveness of a broad range of interventions to combat pre- and post-natal anxiety and depression that extend beyond psychotherapy and pharmacotherapy (Gemmell, Milgrom, & Highet, 2015). Women may benefit from a range of treatments and supports delivered by professionals, semiprofessionals, or volunteers. Within the military, this integrated approach requires collaborative efforts between physicians, nurses, psychologists, social workers, and non-professionals.

The M-O-M-STM program was designed to be a low-cost intervention provided by volunteers guided by perinatal and obstetrical nurses. The results provide evidence for the effectiveness of this simple intervention for decreasing prenatal maternal anxiety and depression. Within a military environment, this type of support is particularly needed and bachelors prepared nurses are educated to provide evidence-based interventions. The masters prepared nurses can lead the efforts and the growing body of nurses within the military with nursing practice doctorates can and should develop processes by which the nurse-led programs are evaluated and sustained.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

Prenatal maternal anxiety is increasingly recognized as a significant public health problem (Matthey, Fisher, & Rowe, 2013; Yawn, LaRusso, Bertram, & Bobo, 2015). There is a need for evaluation of programs based on evidence of improved outcomes (Yawn et al., 2015). The M-O-M-STM program was methodically designed based on a large longitudinal dataset from military women. The program was piloted and now tested with a larger randomized sample. The findings reflect the program's effectiveness at decreasing prenatal maternal anxiety and depression. Decreased numbers of women attending the Pregnancy Centering program precluded our ability to assess the use of the two programs together. The M-O-M-STM is meant to complement the Pregnancy Centering program which is a group prenatal program rather than a support program focused on providing prenatal esteem-building support.

While most military treatment facilities have implemented prenatal assessment programs, a comprehensive evaluation program needs to be implemented across all the treatment facilities in order to compare the assessments and interventions with health outcomes. The Joint Program Committee (JPC) exists to evaluate programs for use across all the services. The Military, Family, and Community Psychological Health and Resilience working group (JPC-5) has funded a project to evaluate pregnancy and birth outcomes for women attending the M-O-M-STM program. The program is anticipated to recruit women from large Navy and Army bases. The team is working with the DHA/MFM consultant to transition the findings from the current study for implementation in military obstetrical services and update the upcoming VA/DoD Clinical Practice Guidelines. Veterans Administration facilities providing obstetrical care to veterans have indicated an interest in the program. We are determining a plan for transitioning the program to the VA.

Consideration needs to be given to adding a component to the post-deployment survey regarding individuals who experienced the birth of a child during the deployment. These service members and their families may require additional support and resources. While all service members and their families struggle with re-integration of the deployer back into the family unit, those that have experienced the birth of a child during their deployment are likely to have increased anxiety and depression. The returning service member will not only be dealing with the re-integration back into his stateside life but he will be dealing with paternal adaptation issues as he discovers what it means to be a father of a new baby and a husband/partner to a woman who may have dramatically changed as a result of the pregnancy and the birth of their child.

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Summary of Dissemination

| Type of Dissemination | Citation | Date and Source of Approval for Public Release |
|-----------------------|---|--|
| Publications | Weis, K. L. & Elmore, K. O. (2017). Current military perinatal mental health treatment models. In M. Thiam (Ed.), <i>Perinatal mental health and the military family: Identifying and treating mood and anxiety disorders</i> (pp. 151-165). New York: Routledge. | 1-Feb-2016 (PAO# 16094) |
| Podium Presentations | Weis, K., Lederman, R., Walker, K., & Chan, W. (2017). Mentors offering maternal support reduces prenatal, pregnancy-specific anxiety in a sample of military women. <i>Journal of Obstetric, Gynecologic, & Neonatal Nursing</i> , 46(5), 669-685. | 20 September 2013 (PAO#FWH20120012H) |
| | Weis, K. (2013). <i>Mentors offering maternal support (M.O.M.S.): A military intervention program for decreasing maternal anxiety and depression and building resilience</i> . (podium presentation, U.S. Army Academy of Health Sciences Graduate School Research Day, Fort Sam Houston, TX, December 11, 2013). | 11 December 2013 (PAO#14032) |
| | Weis, K., Greene, E., & Thiam, M. A. (May, 2014). <i>Perinatal mental health and the military family</i> . Panel presentation at the American Psychiatric Association's 167 th Annual Meeting, New York. | 23 January 2014 (PAO#14037) |
| | Lederman, R. P., Weis, K., & Roberts-Gray, C. (2015, February). Preterm birth and anxiety in low and high-risk women: Selecting anxiety measures and interventions. In C. R. France (Ed.), <i>Society of Behavioral Medicine, 36th Annual Meeting and Scientific Sessions</i> , 49(S1), S54 | 24 January 2015 (PAO#15044) |

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| | <p>Weis, K., Lederman, R., Walker, K., Valentin, M. & Chan, W. (2016). <i>Mentors offering maternal support (M-O-M-STM): Findings from a randomized control trial of program effectiveness</i>. (podium presentation, 9th Annual UIW Research Week, San Antonio, TX, Feb 22-26, 2016).</p> <p>Weis, K. L. (2016, April). <i>Prenatal psychosocial health and birth outcomes in a military population</i>. Panel member for the Military Women's Health Research Conference, Washington, District of Columbia.</p> <p>Weis, K. L., Lederman, R. P., Walker, K. C., & Chan, W. (2017, July). <i>Longitudinal evaluation of a prenatal mentoring program for decreasing maternal anxiety in a military sample</i>. Paper presentation at the Sigma Theta Tau 28th International Nursing Research Congress, Dublin, Ireland.</p> | <p>04 Dec 2015 (PAO#16046)</p> <p>11 May 2016 (PAO#16180)</p> <p>23 Feb 2017 (PAO#17037)</p> |
| Poster Presentations | <p>Weis, K. (2012). <i>Mentors offering maternal support (M.O.M.S.): Building resilient military families</i>. (poster presentation, Federal Nursing Research Poster Presentation – AMSUS, accepted but not presented secondary to AMSUS being canceled).</p> <p>Powel, L. (2013, October). <i>Dads' adaptation during deployment (DADDs): A narrative analysis</i>. Poster presentation at the 19th Qualitative Health Research (QHR) Conference, Halifax, Nova Scotia, Canada.</p> <p>Weis, K. (2014, April). <i>Mentors offering maternal support (M.O.M.S.): A military intervention program for decreasing maternal anxiety and depression and building resilience</i>. A poster presentation, Society of Behavioral Medicine (SBMC), Philadelphia, PA.</p> | <p>6 November 2012 (PAO#13017)</p> <p>23 October 2013 (PAO#13122)</p> <p>23 January 2014 (PAO#14037)</p> |

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| | Medicine, 38th Annual Meeting and Scientific Session, San Diego, CA. | |
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| | <p>Weis, K., Powel, L. (2014, April). <i>Adherence to mission requirements and involvement in wives' pregnancy within the context of military deployment</i>. A poster presentation, Society of Behavioral Medicine, San Antonio, TX.</p> <p>Weis, K. (2014, September). <i>Mentors offering maternal support (M.O.M.S.): An integrated nursing intervention targeting maternal anxiety, depression, coping, and resilience for improved birth outcomes</i>. A paper presentation, TSNRP Research and Evidence Based Practice Dissemination Course, San Antonio, TX.</p> <p>Weis, K., Lederman, R., Morgan, B., & Chan, W. (2016, March). <i>Mentors offering maternal support (M-O-M-STM): Findings from a randomized control trial</i>. A poster presentation, Society of Behavioral Medicine 37th Annual Meeting & Scientific Sessions, Washington, D.C.</p> <p>Weis, K., Lederman, R., Morgan, B., & Chan, W. (2016, September). <i>Mentors offering maternal support (M-O-M-STM): Findings from a randomized control trial</i>. A poster presentation, Ila Faye Miller School of Nursing: Sister Charles Marie Frank Lecture Poster Session UIW, San Antonio, TX, Sept 27, 2016.</p> | <p>27 January 2014 (PAO#15049)</p> <p>30 June 2014 (PAO#14140)</p> <p>1 Feb 2016 (PAO #16077)</p> <p>29 Aug 2016 (PAO#16291)</p> |
| Other | <p>Weis, K. (2015, March 27). <i>Building a theory-based intervention</i>. Plenary Address at the Sigma Theta Tau Epsilon Nu Chapter Dr. Linda Corson Jones Scholarship Day, New Orleans, LA.</p> <p>Weis, K., Lederman, R., Walker, K., Paden, R., & Chan, W. (2017, March). <i>Predictors of increased prenatal maternal anxiety, self-esteem, and resilience in a sample of military women</i>. In K. Weis (Chair), <i>Prevalence and predictors of depression and stress in diverse samples of pregnant women</i>. Symposium conducted at the Society of Behavioral</p> | <p>24 April 2015 (PAO#15095)</p> <p>20 October 2016 (PAO#16353)</p> |

| Reportable Outcomes | |
|--|--|
| Reportable Outcome | Detailed Description |
| Applied for Patent | Application for patent submitted in May 2013 for the M-O-M-S TM program. Intent for patent was for the M-O-M-S TM program process/classes to be used within public health and military health clinic, physicians' offices, social worker, and mental health settings. The patent would include a training defined mentor component in addition to the M-O-M-S TM class sessions. Patent was not processed fully as the USAF determined it had other more pressing patent requests to process - denied on 20 May 2014. |
| Issued a Patent | Patent not fully processed or issued through the USAF |
| Developed a cell line | NONE |
| Developed a tissue or serum repository | NONE |
| Developed a data registry | NONE |

Recruitment and Retention Table

| Recruitment and Retention Aspect | Number |
|---|--------|
| Recruitment information for the Husbands' portion of the study | |
| Subjects projected in grant application | 67 |
| Subjects available | |
| Subjects contacted or reached by approved recruitment method | 23 |
| Subjects screened | 47 |
| Subjects ineligible | 31 |
| Subjects refused | 8 |
| Human subjects consented | |
| Subjects who withdrew | 1 |
| Subjects who completed study | 8 |
| Subjects with complete data | 8 |
| Subjects with incomplete data | 0 |

Demographic Characteristics of the Sample

| Characteristic – Wives portion of the study | Total Cohort <i>n</i> =246 |
|--|-------------------------------|
| Age (yrs) | 28.72 ± 5 |
| Marital Length | 4.67 ± 3.8 |
| Women, Active Duty & Dependent Wives, <i>n</i> (%) | 246 (100) |
| Race | <i>n</i> (%) |
| White, nonHispanic | 147 (60) |
| Black, nonHispanic | 29 (12) |
| Hispanic or Latino | 54 (22) |
| Asian or Other Pacific Islander | 13 (5) |
| American Indian/Alaskan Native | 2 (0.8) |
| Other | 1 (0.4) |
| Marital Status | |
| Married | 225 (91) |
| Not Married | 21 (9) |
| Military Services of All Participants | |
| Air Force | 156 (64) |
| Army | 59 (24) |
| Navy | 22 (9) |
| Marine | 7 (3) |
| Coast Guard | 2 (0.8) |
| Service Component | |
| Active Duty Women, All Services | 97 (39) |

| Recruitment and Retention Aspect | Number |
|--|---------|
| Recruitment information for the Wives' portion of the study | |
| Subjects projected in grant application | 648 |
| Subjects available | |
| Subjects contacted or reached by approved recruitment method | 3576 |
| Subjects screened | 4704 |
| Subjects ineligible | 1128 |
| Subjects refused | 1081 |
| Human subjects consented | 367 |
| Subjects intervention group/control group | 187/180 |
| Intervention group/control group subjects who withdrew | 69/52 |
| Intervention group/control group subjects who completed study | 118/128 |
| Intervention group/control group subjects with complete data | 103/118 |
| Intervention group/control group subjects with incomplete data | 15/10 |

Table 1. Psychosocial Study Variables

| Variable | Measurement | Collection Timepoints |
|--|--|--|
| Prenatal Maternal Stress and Anxiety – Prenatal Adaptation | Lederman Prenatal Self-Evaluation Questionnaire (PSEQ), 53 items (7 scales). Higher scores on a scale indicate greater anxiety related to the formulation of the motherhood role. Biochemical markers of stress in labor, and labor and postpartum outcomes were used to provide convergent and divergent construct validity; Cronbach's alpha coefficients for the scales range from $\alpha = .75$ to .92. Weis obtained similar coefficients in her military populations. The instrument has been factored with a military population and all 7 scales remained distinct. The scales measure the level of anxiety the woman is experiencing relative to the particular dimension. | Pregnancy: 1st, 2nd and 3rd trimesters |
| Self-Esteem | Rosenberg Self-Esteem Scale (RSE), 10-item scale measuring the degree to which one values oneself. The possible range of scores is 10 to 40, with higher scores indicating higher self-acceptance. The Cronbach's alpha reliabilities range from .84 to .90. The construct validity of the instrument was demonstrated by examining its conformity to theoretical predictions. The test-retest reliability was found to be $r = 0.85$. This instrument was used in the pilot M.O.M.S. project with good results. | Pregnancy: 1st, 2nd and 3rd trimesters |
| Prenatal Depression | The Edinburgh Postnatal Depression Scale (EPDS) is a 10-item self-report scale validated for use during pregnancy and the postpartum period. Scores range from 0-30; higher scores are associated with higher depression. Scores of 12 or greater will be associated with prenatal depression. The Cronbach's alpha has been established as 0.80. | Pregnancy: 1st, 2nd and 3rd trimesters |
| Perceived Support | The Social Support Index (SSI) is a 17-item instrument designed to measure the degree to which families are integrated into the community, view the community as a source of support, and feel that the community can provide emotional, esteem, and network support. The instrument uses a 5-point Likert scale with higher scores indicating more perceived, anticipated social support. The SSI had a .40 validity coefficient with the criterion measure of family well-being. Construct validity was assessed in a study with over 1,000 families and the perceived support was positively correlated with a family's sense of fit within the community ($r = .40$). The internal reliability of the SSI was reported as $\alpha = .82$ and test-retest reliability as $\alpha = .83$. | Pregnancy: 1st, 2nd and 3rd trimesters |

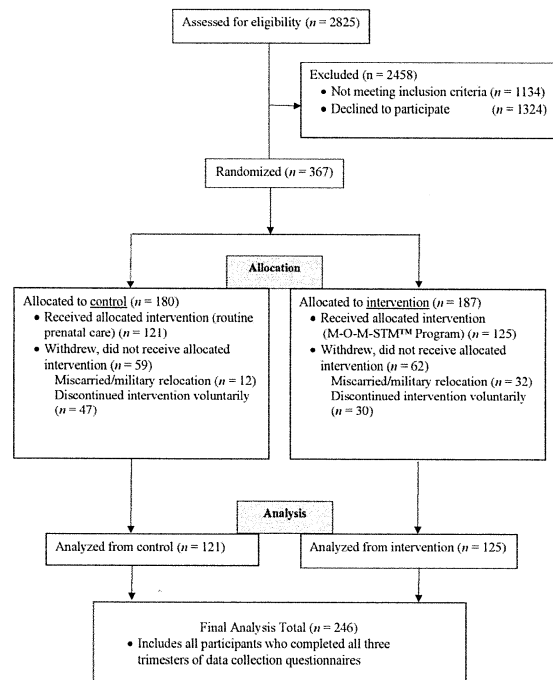


Figure 1. CONSORT Diagram for study profile, participant contact and retention

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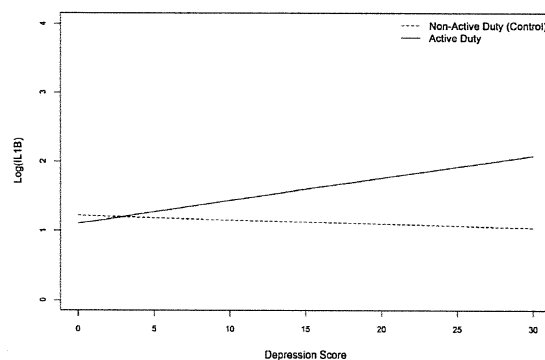


Figure 3. Interaction of active duty status and depression scores to IL-1B values

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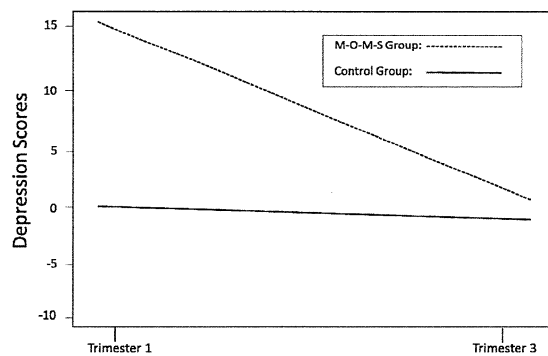


Figure 2. Interaction of group assignment and deployment of spouse to depression scores

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Program Budget Summary Report

Company: The Geneva Foundation
User: chappin@corp.genevafund.org

Period Start Date: 8/1/2011
Period End Date: 8/30/2017



Contract: 10226 - Maternal Offspring Maternal Support (MOMS) Bur
Award Amount: \$71,456.00
Total Estimated: \$71,456.00
Total Funded: \$71,456.00

Contract P# 8/1/2011 - 73110017
Customer: TRISERVICE NURSING RESEARCH PROGRAM
Customer Contract ID: HU001111-1-1513
Contract Manager: Robinson, Kathleen

| Category | Personnel | Travel | Equipment | Supplies | Other | Contractor | Total |
|---------------------------------------|-------------------|-------------------|-------------------|-------------|-------------------|------------------|---------------------|
| Direct Expenditures | | | | | | | |
| Personnel | | | | | | | |
| Personal Salary & Wages | 508,683.10 | 433,790.18 | 433,790.18 | 0.00 | 433,790.18 | 24,602.82 | 1,814,656.46 |
| Fringe Benefits (Burton) | 0.00 | 24,602.82 | 24,602.82 | 0.00 | 24,602.82 | 24,602.82 | 74,413.54 |
| Total Personnel | 508,683.10 | 508,675.46 | 508,675.46 | 0.00 | 508,675.46 | 74,413.54 | 2,050,873.04 |
| Non-Personnel | | | | | | | |
| Equipment | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Travel | 12,631.02 | 12,631.02 | 12,631.02 | 0.00 | 12,631.02 | 0.00 | 38,524.08 |
| Supplies | 11,661.19 | 11,661.19 | 11,661.19 | 0.00 | 11,661.19 | 0.00 | 35,044.57 |
| Other | 29,252.69 | 33,252.69 | 33,252.69 | 0.00 | 33,252.69 | 0.00 | 96,011.16 |
| Contractor | 33,426.00 | 33,426.00 | 33,426.00 | 0.00 | 33,426.00 | 0.00 | 99,708.00 |
| Subcontractor | 126,921.00 | 126,921.00 | 126,921.00 | 0.00 | 126,921.00 | 1.96 | 383,794.96 |
| Total Non-Personnel | 215,162.90 | 235,098.94 | 235,098.94 | 0.00 | 235,098.94 | 1.96 | 725,362.78 |
| Total Direct Expenditures | 723,846.00 | 743,774.40 | 743,774.40 | 0.00 | 743,774.40 | 76.50 | 2,776,235.82 |
| Indirect Expenditures | | | | | | | |
| G&A Burden | 139,961.00 | 126,113.39 | 126,113.39 | 0.00 | 126,113.39 | 13,837.02 | 395,025.79 |
| Other Indirect Costs | 177.73 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 177.73 |
| Total Indirect Expenditures | 139,961.00 | 126,113.39 | 126,113.39 | 0.00 | 126,113.39 | 13,837.02 | 395,203.51 |
| Total Gr. + Indr. Expenditures | 863,807.00 | 869,887.79 | 869,887.79 | 0.00 | 869,887.79 | 90.50 | 3,171,439.33 |
| Fee Amount | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Total Expenditures + Fee | 863,807.00 | 869,887.79 | 869,887.79 | 0.00 | 869,887.79 | 90.50 | 3,171,439.33 |

Report Date: 10/25/2017

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